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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,803

01/23/2007

Patrick Soon-Shiong

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03/30/2009

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

03/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,803	Applicant(s) SOON-SHIONG ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55-63, 65-73, 75-83, 85-93, 95 and 96 is/are allowed.
- 6) ☒ Claim(s) 64, 74, 84, 94 and 97-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on March 4, 2009, the applicants have filed a RCE and furthermore, have amended claims 55-100, 107 and 108.

2. Claims 55-108 are pending in the application.

Response to Arguments

3. Applicant's arguments filed on March 4, 2009 have been fully considered but they are not persuasive regarding enablement rejection of claims 97-108. The applicants have amended claims to overcome indefiniteness rejection. The examiner also agrees with the applicants arguments that the compounds 6-9 disclosed by Du publication are only synthetic intermediate compounds in the synthesis of DB-67 and therefore, it would not have been obvious to one skilled in the art to select this intermediate for further development of camptothecin diesters. In regard to enablement rejection of claims 97-108, the examiner does not agree with the applicants arguments that applicants discovered that the instant compounds are topoisomerase I inhibitors and furthermore, to have activity against a wide range of cancers. First of all, there is no teaching or experimental data to show that the instant compounds are inhibitors of topoisomerase I activity. Secondly, the only cancer cell line used in the instant specification is human

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breast carcinoma. The applicants mention article by Takimoto et al. However, the applicants did not enclose copy of this article for proper evaluation.

Conclusion

4. Rejection of claims 97-108 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 64, 74, 84 and 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 recites the limitation "C4-C10 aryl for variable R5" in claim 55. There is insufficient antecedent basis for this limitation in the claim.

Claim 74 recites the limitation "C4-C10 aryl for variable R5" in claim 55. There is insufficient antecedent basis for this limitation in the claim.

Claim 84 recites the limitation "C4-C10 aryl for variable R5" in claim 55. There is insufficient antecedent basis for this limitation in the claim.

Claim 94 recites the limitation "C4-C10 aryl for variable R5" in claim 55. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 55-63, 65-73, 75-83, 85-93, 95 and 96 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

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(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625